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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,075	07/19/2001	Jean Barbeau	955.117USWO	8384

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EXAMINER

WINTER, GENTLE E

ART UNIT	PAPER NUMBER
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1746

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,075

Applicant(s)

BARBEAU ET AL.

Examiner

Gentle E. Winter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 42 and dependant claims 45-46, 48 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 42 and dependant claims 45-46, 48 and 71 claim a method further comprising a “bactericidal amount of bactericide”. This claim is indefinite because:

- a. The claim fails to mention how claims 42 and 71 further limit their base claims;
and
- b. Seemingly bactericide is in any concentration is a bactericidal amount of
bactericide.

The claim is in improper form, fails to further limit, and is ambiguous. In the interests of compact prosecution the claim is construed to require any amount of a substance having bactericidal properties, and that there is a step of “providing a bactericidal amount of a bactericide”.

4. Claim 41 is indefinite because the discussion of “salt” appears to at once contemplate the salt as being optional and required. It is assumed that the sentence intends to convey that when a salt is used the salt must have the enumerated characteristics.

5. In claim 79, the recitation of “at least about” is indefinite. The expression has been construed to reflect either of two optional scenarios, i.e. either as “at least” or as “about”. As

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such 18-24 hours would constitute "at least one hour" and is therefore anticipated. If applicant intended to recite "about 8 hours" applicant must amend the claim to so state.

Claim Objections

6. The following claims are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

7. Claims 42, 69, and 72 recites a method containing a bactericide. This reflects improper form for a method claim.

8. In claim 1 "dislodge" is misspelled second line form the bottom.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 41-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent No. 5,731,275 and Applied and Environmental Microbiology by Nishiguchi et al. (Nishiguchi)

10. With respect to claims 41-80 drawn to a method for removing a biofilm from a surface, which comprises the step of contacting said surface with a composition comprising an effective

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dislodging amount of a detergent and an effective dislodging amount of an acid or a salt of an acid, said salt being capable of displacing divalent cations present in the structure of said biofilm, for a time sufficient to dislodge said biofilm, all percentages representing weight per volume concentrations. With the proviso that said composition is not a mixture achieving an aqueous final concentration of SDS 1 % - 2 % and EDTA 1%, or SDS 1% - 2% and mandelic and lactic acids, each at an individual concentration of 1% or in a combined concentration of 2%. The '275 reference identically discloses each and every limitation of claim 41 except that the '275 patent fails to explicitly disclose a composition outside the indicated excluded range. See e.g. column 3, line 29 *et seq.*

11. Sodium dodecyl sulfate (SDS) is an anionic detergent with a long hydrophobic tail that binds to the hydrophobic side chains of amino acids at a constant ratio of 1.4g of SDS to 1g of polypeptide, proportional to the molecular weight of the protein (Hames, 1998). The artisan would have been motivated to select a quantity of SDS, which has the requisite lysing (aid) efficacy. The SDS is integral to the creation of holes in the cell membranes.

12. The above recited proportion (1.4:1) ties protein denaturing efficacy with SDS concentration, admittedly this may periodically include a 1-2% SDS solution but it need not. For example Nishiguchi discloses a DNA extraction protocol utilizing an 0.1% SDS, NaCl, and EDTA.

13. The motivation for modifying the references is in the references and in the knowledge generally available to one of ordinary skill in the art. Specifically, the primary reference discloses that the disclosed composition is the preferred composition. The prior art of record is replete with teaching showing the interrelationship between the concentration of SDS and

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cleaning efficacy and the secondary reference actually teaches the claimed composition for the purpose of denaturing proteins a critical step in the biofilm removal process of the '275 patent.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

United States Patent Nos. 5,942,480, 5,759,970 both disclose all of the limitations of the instant invention with the exception of failing to disclose a range outside the excluded range. Any or all of these references are believed sufficient to support a finding of obviousness in view of the recent case from the U.S. Court of Appeals for the Federal Circuit *In Re Lance G. Peterson* 02-1129. In the decision the Court affirmed the Board's determination that the claimed range of "about 14 percent chromium" encompassed Wukusick's teaching to use upto 12 percent chromium. In the instant case the prior art of record discloses the exact values excluded from the claims. For this reason the claims would seeming contemplate a solution having 1.99 percent SDS. As such the claims would properly be rejected relying on the exact motivation of the prior art of record.

United States Patent No. US 5,910,420 is considered to provide an anticipatory reference to at least the independent claims 41, 68, 70 and 76.

The SDS-PAGE system which is well known in the art relies on an *inter alia* 0.1% SDS, EDTA, salt solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gentle E. Winter whose telephone number is (703) 305-3403. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

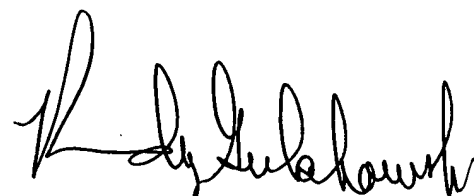
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (703) 308-4333. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Gentle E. Winter
Examiner
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January 23, 2003

A handwritten signature in black ink, appearing to read "Randy Gulakowski", is written over a rectangular area.

RANDY GULAKOWSKI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700